

### **REMARKS**

Upon entry of this Amendment, claims 1-20 will be pending in the present application. Claims 5-8, 17 and 18 were previously withdrawn from consideration. Claim 16 is herein amended. New claims 19 and 20 are herein added. No new matter has been entered. It is respectfully submitted that this Amendment is fully responsive to the Office Action dated July 20, 2007.

### **Objections to the Specification**

The abstract was objected to because it was in improper format. To overcome this objection, Applicants herein amend the Abstract to comply with USPTO requirements. Accordingly, Applicants request that the objection to the specification be withdrawn.

### **Claim Objections**

Claim 16 was objected to as depending from a non-elected claim. To expedite prosecution, Applicants herein amend claim 16, in part, to depend from claim 1. Accordingly, Applicants request that the objection to claim 16 be withdrawn.

### **Claim Rejections – 35 U.S.C. §102 (*Tsai et al.*)**

Claims 1, 2, 10, 11, and 16 were rejected under 35 USC §102(b) as anticipated by *Tsai et al.* However, for at least the following reasons, Applicants disagree with the anticipation rejection of these claims

Anticipation requires the disclosure in a single prior art reference of each and EVERY element of the claimed invention, arranged as in the claim. Lindemann Maschinenfabrik GMBH v. American Hoise and Derrick Co., 221 USPQ 481, 485 (Fed. Cir 1984).

However, *Tsai et al.* fails to disclose or suggest at least “floculant for flocculating protein” in the configuration of the measuring kit of the invention. See claim 1. Instead, for example, *Tsai* discloses an invention relating to an improvement of “Coupled filtration/bioluminescence (F/B) system” that utilizes a filtration procedure so as to minimize the effects of nonmicrobial ATP (free ATP) and other soluble substances. The F/B system measures the ATP of microbial cells collected on a filter by a bioluminescent reagent. Thus, the F/B system measures a quantity of microbes by use of correlation between the measured ATP quantity and the measured microbe quantity. The F/B system includes filters of different cell sizes so as to separate different kinds of microbes by their cell sizes and measure respective microbe quantities. See page 74, left column and Fig. 1 of *Tsai*.

Accordingly, *Tsai* uses two filters having different pore sizes (first filter of large pore diameter and second filter of small pore diameter) to filter a liquid sample of microbes, as shown in Fig. 1. At this time, the two filters of different pore diameters are used for separating microbes or bacteria of different sizes. That is, the filters are provided just for collecting or picking up the microbes (microbe ATP) themselves as a measured object.

In contrast, though the measuring kit of the invention has two filters of different pore diameters, the first filter has a large pore diameter such that it passes the microbes themselves as the measured object, while collecting or picking up body cells or proteins (flocculated proteins)

that hinder measurement. Moreover, the second filter has a small pore diameter such that it collects or picks up the microbes themselves as the measured object, while passing the free ATP that hinders measurement. Therefore, the measuring kit of the invention includes the flocculant for proteins so as to flocculate proteins and collect proteins on the first filter.

Applicants submit that *Tsai* fails to disclose or suggest the flocculant for proteins that are used for the aforementioned purpose. For instance, if it is supposed that the two filters of different pore diameters in *Tsai* are equivalent to the two filters of the invention and that *Tsai* picks up the body cells on the first filter (actually picking up microbes of large size) and the microbes on the second filter, *Tsai* never discloses or suggests an idea of picking up proteins on the first filter. To the contrary, *Tsai* is designed such that the “soluble ATP and other interfering substances”, which hinder the microbe measurement, pass or escape “both filters” (page 76, ll. 2 to 4). Namely, even if the liquid sample of *Tsai* contains proteins, the proteins are designed to pass through both the filters while solved in the liquid sample. Consequently, *Tsai* fails to disclose or suggest at least “flocculant for flocculating protein” in the configuration of the measuring kit of the invention.

Moreover, Applicants respectfully point out that the syringe pump of *Tsai* which the Examiner indicates as “flocculant” has a completely different meaning from a commonly known flocculant (as a chemical agent), even if it may perform a mechanical flocculating function. Particularly, since *Tsai* has no description on treatment of protein in the liquid sample in any way, a person skilled in the art would not recognize the syringe pump of *Tsai* as a member acting to flocculate the protein as in the “flocculant” of the present invention.

Accordingly, Applicants submit that *Tsai* does not anticipate claim 1 of the present invention because the reference fails to disclose or suggest at least “flocculant for flocculating protein” in the configuration of the measuring kit of the invention.

In addition, Applicants submit that claim 1 is not anticipated by *Tsai*, because the reference only describes using one syringe; whereas the present invention uses two kinds of syringes (first syringe and second syringe). Moreover, Applicants herein add new claim 19 to distinguish the present invention more clearly from *Tsai* by limiting the structure and function of the second syringe. Support for this new claim is found, for example, in paragraph [0078] of the original specification. Accordingly, Applicants submit that *Tsai* does not anticipate claim 1 (or claim 19) of the present invention because the reference fails to disclose or suggest a measuring kit comprising two kinds of syringes.

In addition, Applicants submit that *Tsai* fails to disclose or suggest the washing liquid of the invention (e.g., claim 1) or the 60% to 100% by content of a sterile distilled water solution of an ethanol or 1% by content to 8% by content of a sterile distilled water solution of a DMSO. See claim 20. Support this new claim is found, for example, in paragraphs [0095] to [0096] of the original specification. Instead, Applicants submit that the phosphoric acid buffer solution of *Tsai* will possibly become a factor of instability of a test result, as described in Paragraph [0008] of the original specification of the present application. Accordingly, Applicants submit that *Tsai* does not anticipate claim 1 (or claim 20) of the present invention.

In addition, Applicants submit that *Tsai* fails to disclose or suggest including *a bacteriolytic agent for dissolving the microorganisms trapped on the second filter so as to*

*dissolve out ATP*. See claim 1. Instead, for example, the bacteriolytic agent (Lysostaphin) used in *Tsai* requires additional incubation. Accordingly, Applicants submit that *Tsai* does not anticipate claim 1 (or claims 13 and 14) of the present invention

In addition, Applicants submit that *Tsai* fails to disclose or suggest the “sterile distilled water” for making the solid or high viscosity sample of the present invention into a liquid sample. That is, it is only the “phosphoric acid buffer agent” that is suggested in *Tsai* as an agent used for making the solid sample into the liquid sample. The “sterile distilled water” for making the solid or high viscosity sample of the present invention into a liquid sample is recited in claim 16. Accordingly, Applicants submit that *Tsai* does not anticipate claim 1 (or claim 16) of the present invention.

In view of the aforementioned remarks, Applicants respectfully submit that *Tsai* does not anticipate the above-identified claims of the present invention. Accordingly, Applicants request that the anticipation rejection of these claims be withdrawn.

**Claim Rejections – 35 U.S.C. §102 (*Trudil*)**

Claims 1, 2, and 4 were rejected under 35 USC §102(b) as anticipated by *Trudil* (U.S. Pat. No. 6,395,504B1). However, for at least the following reasons, Applicants disagree with the anticipation rejection of these claims

Anticipation requires the disclosure in a single prior art reference of each and EVERY element of the claimed invention, arranged as in the claim. Lindemann Maschinenfabrik GMBH v. American Hoise and Derrick Co., 221 USPQ 481, 485 (Fed. Cir 1984).

However, *Trudil* fails to disclose or suggest the “flocculant for flocculating protein” for flocculating the proteins and picking up them on the first filter as in the present invention. Claim 1. For instance, neither the term “flocculant” nor its derivatives (flocculate, flocculation, etc.) are used in *Trudil*. Moreover, *Trudil* does not disclose any of the chemicals recited by the Applicant, in claims 9, 17 and 18, for use as flocculants (*i.e.* “an aliphatic alcohol such as ethanol, a carboxylic acid such as a benzoic acid or a salicylic acid, a chitosan or a chitosan oligosaccharide”). Since *Trudil* contains no description on treatment of protein in the liquid sample in any way, a person skilled in the art would not conceive a use of the above-mentioned “flocculant for flocculating protein” of the present invention. Accordingly, Applicants submit that the cited reference does not anticipate claim 1 of the present invention.

Moreover, Applicants submit that there is no teaching or suggestion of use of two syringes or two filter cases (different pore diameters) that remove unnecessary somatic cells, proteins or free ATP so as to pick up only microbes as an object, as in the present invention. Instead, Applicants submit that *Trudil* only discloses one syringe and one filter in the specification and drawings. Thus, *Trudil* does not anticipate claim 1 because *Tsai* uses only one syringe, whereas the claimed invention recites two kinds of syringes (first syringe and second syringe). See claim 1.

In view of the aforementioned remarks, Applicants respectfully submit that *Trudil* does not anticipate the above-identified claims of the present invention. Accordingly, Applicants request that the anticipation rejection of these claims be withdrawn.

**Claim Rejections – 35 U.S.C. §103**

Claims 1-4 and 9-16 were rejected under 35 U.S.C. §103(a) as unpatentable over the combination of *Tsai et al.* in view of *Trudil et al.* and *Tanaka et al.* However, for at least the following reasons, Applicants disagree with the rejection of these claims

As described above, *Tsai* and *Trudil* fail to disclose or suggest at least the “flocculant for flocculating protein” recited in claim 1 of the present application. Accordingly, even if one were to combine these references (which Applicants disagrees with) with *Tanaka*, the result would not be the claimed invention.

Moreover, Applicants submit that the “filtering accelerating agent” of the present invention is not disclosed or suggested in any of the cited references. Accordingly, even if one were to combine the cited references, the result would not be the claimed invention.

In view of the aforementioned remarks, Applicants respectfully request that the obviousness rejection of these claims be withdrawn.

**Conclusion**

In view of the aforementioned amendments and accompanying remarks, Applicants submit that the claims, as herein amended, are in condition for allowance. Applicants request such action at an early date.

Application No. 10/529,854  
Attorney Docket No. 052343

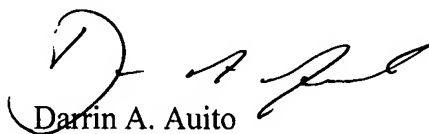
Amendment under 37 C.F.R. §1.111  
Amendment filed January 22, 2008

If the Examiner believes that this application is not now in condition for allowance, the Examiner is requested to contact Applicants' undersigned attorney to arrange for an interview to expedite the disposition of this case.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

**WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP**

A handwritten signature in black ink, appearing to read "Darrin A. Auito". The signature is fluid and cursive, with a large initial "D" and a long, sweeping underline.

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